K020221

APR 2 2 2002

Summary of Safety and Effectiveness

Applicant/Sponsor: Industrias Quirurgicas de Levante, S.L.
Islas Baleares, 50
Poligono Fuente del Jarro
Paterna, Valencia Spain 46988
Establishment Registration Number: 9610576

Contact Person: Lonnie Witham
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587
Fax: (219) 372-1683

Proprietary Name: IQL Basic Fragment Plate Set, IQL Basic Fragment Screw Set, IQL Small Fragment Set, IQL Mini Fragment Set

Common or Usual Name: Stainless Steel Bone Plates & Bone Screws

Classification Name: Plate, Fixation, Bone (21 CFR 888.3030)
Screw, Fixation, Bone (21 CFR 888.3040)

Device Classification: Class II

Device Product Code: HRS (plates), HWC (screws)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed: These devices are substantially equivalent to various stainless steel bone plates and screws sold by Biomet Inc. (OEC) prior to May 28,1976. Similar devices were included in the Kirschner (Biomet) Small Fragment Fixation System cleared under K864924 in March 1987.

Device Description: IQL Bone Plates and Screws are used for the same indications as stainless steel bone plates and screws that have been commercially available continually since the 1950s. These devices are to be implanted by insertion into bones for fixation of fractures, or the fixation of bones that have been surgically prepared (osteotomy) for correction of deformity, or arthrodesis. Bone screws are used to attach the plates to the bone and stabilize bone fragments until bone union has occurred. A wide variety of bone plates similar to those included in this submission have been in commercial distribution since prior to May 28, 1976.

Intended Use: IQL Bone Plates and Screws are used for adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones.

Summary of Technology: This device utilizes standard technology that is commonly known by physicians. This technology has been used in commercially available metallic internal fixation devices prior to May 28, 1976. The stainless steel used to manufacture these inplants conforms to material standards published by the American Society for Testing and Materials ASTM F-138 and ASTM F-139.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2002

Mr. Lonnie Witham
Biomet, Inc.
P.O. Box 587
Warsaw, In 46581-0587

Re: K020221
Trade/Device Name: IQL Stainless Steel Bone Plates and Screws – Various Styles
Regulation Number: 21 CFR 888.3030 and 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 21, 2002
Received: January 22, 2002

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K020221

Device Name: IQL Stainless Steel Bone Plates & Screws – Various Styles

Indications for Use:

IQL Bone Plates and Screws are used for adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020221